

Patent Application
Atty. Docket No. 25301A

REMARKS

As discussed herein, Applicants respectfully request reconsideration and withdrawal of the rejections of record.

Status of the Claims

Claims 1-12 were originally pending and stand rejected. Claims 1-12 are now canceled without prejudice or disclaimer by this Amendment. New claims 13-20 are presented herewith.

Response to Written Description Rejection

Claim 11 is rejected under 35 USC § 112, ¶ 1, as allegedly failing to comply with the written description requirement. The rejection states that the claim reaches out to as-yet undiscovered diseases.

In order to expedite prosecution, claim 11 has been canceled without prejudice or disclaimer and replaced with claims 19 and 20. New claims 19 and 20 are not specifically limited to attaining treatment or prevention of specific diseases. Thus, the rejection is believed to be moot. Reconsideration and withdrawal of the rejection are respectfully requested.

Nonetheless, Applicants respectfully note that claim 11 is an original claim. Thus, there is no lack of written description in the traditional sense because the disclosure *per se* includes a description of the claimed subject matter. There is also no lack of written description in the sense of the requirement as applied in cases such as Univ. California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997) or in the USPTO Examination Guidelines, which have been adopted by the Federal Circuit. This second aspect of the written description requirement requires that the claimed subject matter be described in terms of some structure in combination with function. In contrast to a hypothetical method claim that may recite any "5-HT₄ agonist or antagonist" without regard to structure, claim 11 specifies a definite genus of chemical subject matter. Moreover, the recitation of treating conditions "mediated by 5-HT₄" with the compounds provides a direct technical link between the compounds and their activity disclosed in the specification. Thus, the skilled artisan would recognize that Applicants were in possession of the compounds themselves and their use against diseases mediated by 5-HT₄. Even more than a claim reciting a named disease, claim 11 specifies only conditions mediated by the receptors for which the compounds are known to be active. Thus, Applicants have provided structure and a relationship between structure and function as required by § 112, ¶ 1. Accordingly, Applicants respectfully disagree with the rejection of claim 11.

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Response to Enablement Rejection

Claims 10-12 are rejected under 35 USC § 112, ¶ 1, as allegedly lacking enablement. The rejection states that the 5-HT receptor ligand art is recognized as unpredictable, that slight change in structure would drastically alter affinity and selectivity, that no *in vivo* procedures are described, and that treatment of the claimed diseases is not enabled.

Applicants believe that the rejection is moot in view of new claims 19 and 20, which recite, respectively, agonizing or antagonizing 5-HT₄ in a subject, but are not limited to attaining treatment or prevention of specific diseases. The specification discloses and evidences that the claimed compounds are 5-HT₄ receptor binders, which could easily be tested by the skilled artisan for any individual compounds. Routine screening is not undue experimentation. Wands, supra. Thus, the assertions in the rejection regarding certain diseases are not believed relevant to the new claims. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In addition, Applicants respectfully traverse the assertions and conclusions in the rejection. First, the specification does disclose the use of the claimed compound to treat disease, including dosage levels, and modes of administration, i.e., *in vivo* procedures. See, e.g., pp. 30-32. Here too, the rejection appears to impose an improper requirement that the examples disclose all embodiments within the scope of the claims. Methods for assessing the activity of the compounds are also disclosed. The skilled artisan could thereby use the claimed compounds without undue experimentation. The rejection also asserts that the precise role of 5-HT₄ is not agreed upon. Regardless, the skilled artisan could prepare and routinely test the claimed compounds to determine its specific properties within the claimed genus. Thus, Applicants respectfully traverse the rejection.

Response to Anticipation Rejection

Claims 1-12 are rejected under 35 USC § 102(e), as allegedly being anticipated by US Patent No. 6,624,162 to Uchida et al. ("UCHIDA"). The rejection states that UCHIDA Examples 26 and 28-30 are encompassed by Applicants' claims 1-3 and 10-12, and that the cited examples are identical to Applicants' claims 5-9. Claim 4 is not specifically mentioned.

Section 102(e) of the patent law codifies the traditional law holding that delays of the Patent Office should not delay prior art effects of patent application disclosures. Alexander Milburn Co. v. Davis-Boumonville Co., 270 US 390 (1926). There are at least four requirements that must be met in order for a US patent to anticipate pending claims under §

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102(e). First, the applied patent must be by another. Second, the applied patent must disclose the pending claimed invention. In re Lund, 376 F2d 982 (CCPA 1967). Third, the applied patent must disclose a patentable invention entitled to a filing date before the invention of the pending claimed invention. In re Wertheim, 646 F.2d 527, 539 (CCPA 1981). Fourth, if the application that issued as the applied patent was not filed before the invention of the pending claimed invention, then a parent of the applied patent filed before the invention of the pending claims must disclose the pending claimed invention. In re Klesper, 397 F.2d 882, 886 (CCPA 1968).

Applicants respectfully submit that (1) the application for UCHIDA was not filed before the invention of the present claims and (2) the presently claimed invention was not disclosed in a parent of UCHIDA filed before the invention of the pending claimed invention. Specifically, the present application claims priority of Appln. No. 60/412,485, filed 20 Sep 2002 and the present claims are believed to be entitled to that date as their effective filing date. Further, the application that issued as UCHIDA was filed 20 Sep 2002. Thus, UCHIDA was not filed before the invention of the present claims. The UCHIDA application does claim priority of Appln. No. 30/343,372, filed 22 Oct 2001. However, the subject matter of UCHIDA cited in the rejection (*i.e.*, Examples 26 and 28-30) was not present in the original '372 application filed 22 Oct 2001, but was added at the time of the 20 Sep 2002 application, *i.e.*, not prior to Applicants' priority date. Thus, the presently claimed invention was not disclosed in a parent of UCHIDA filed before the invention of the pending claims. Accordingly, at least the cited portions of UCHIDA are not prior art with respect to the pending claims and the fourth requirement of § 102(e) anticipation is not met for at least this reason. Thus, a Rule 132 declaration regarding inventorship is not believed to be necessary in this case. Accordingly, while the issued *claims* of UCHIDA appear to find clear support in the earlier '372 application, the subject matter added 20 Sep 2002 should not be accorded an earlier date for purposes of § 102(e).

Response to Double-Patenting Rejection

Claims 1-12 are rejected for alleged obviousness-type double patenting over claims 1-5 and 8-11 of UCHIDA and over the "corresponding" claims of Appln. No. 10/716,920. The rejection states that the present claims are not identical to the UCHIDA claims, but that the claims are not patentably distinct, and that the present claims 5-9 are allegedly identical to the preferred compounds within the patented genus of UCHIDA.

Applicants respectfully traverse the rejection. A double patenting analysis must refer to the invention recited in the *claims* of the applied patent, not the entire specification. In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986). Otherwise, a rejection would

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amount to a back-door prior art rejection without establishing whether an applied patent actually is prior art. *Id.* In the present case, use of the entire specification in a double-patenting rejection would amount to treating UCHIDA as prior art to the pending claims. Moreover, absent evidence to the contrary, a claimed genus does not disclose or suggest an included subgenus or species.

Thus, the assertion in the rejection that the claims are not patentably distinct merely because they are encompassed by the UCHIDA claims, and reliance on examples that are not specifically recited in the claims are believed to be improper. Kaplan, supra.

Applicants claim, *inter alia*, a compound of Formula I (above), wherein, R¹ represents hydrogen or a halogen; R² represents methyl or ethyl; R³ represents (a) 3 to 6 carbon branched alkyl or (b) 3 to 6 carbon straight or branched alkyl which is substituted by 1 to 6 carbon alkoxy; with the proviso that when said alkoxy substitutes a terminal carbon, then said alkyl (b) is branched alkyl; including a pharmaceutically acceptable salt thereof.

Other than as discussed above, the rejection gives no reason why any invention defined by UCHIDA *claims* 1-5 would suggest the subgenera or species of Applicants' present claims. To the contrary, examples in Applicants' specification, which are encompassed by the present claims, show significantly improved attributes over comparator compounds. See, e.g., pp. 29-30. Thus, Applicants respectfully submit that all of the present claims are patentably distinct from the cited claims of UCHIDA.

Conclusion

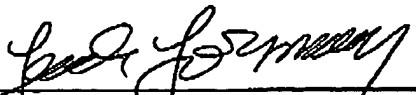
In view of the above, Applicants respectfully submit that all of the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and, as the next official action, to provide a Notice of Allowance.

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If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Date: 25 Oct 04



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